# MAUDE Adverse Event Report: ETHICON, INC. PHYSIOMESH MESH, SURGICAL, POLYMERIC



## ETHICON, INC. PHYSIOMESH MESH, SURGICAL, POLYMERIC

Back to Search Results

**Catalog Number** PHY1015V
**Device Problem** Other (for use when an appropriate device code cannot be identified)
**Event Type** Injury
**Manufacturer Narrative**

(b)(4): allergic reaction. Conclusion: no conclusion can be drawn at this time. Should additional information be obtained, a supplemental 3500a form will be submitted accordingly.

**Event Description**

It was reported that a patient underwent a laparoscopic inguinal hernia repair procedure and mesh was used. The patient experienced an allergic reaction and had to have the mesh removed. Additional information has been requested.

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| | |
|---|---|
| **Brand Name** | PHYSIOMESH |
| **Type of Device** | MESH, SURGICAL, POLYMERIC |
| **Manufacturer *(Section D)*** | ETHICON, INC.<br>Route 22 West<br>Po Box 151<br>Somerville NJ 08876 |
| **Manufacturer *(Section G)*** | ETHICON GMBH & COMPANY KG<br>Robert - Koch - Strasse 1<br>Po Box 1409<br>D-22851 Norderstedt NI<br>GERMANY NI |
| **Manufacturer Contact** | Daniel Lamont<br>Route 22 West<br>Po Box 151<br>Somerville , NJ 08876<br>9082182708 |
| **MDR Report Key** | 2386052 |
| **Report Number** | 2210968-2011-02214 |
| **Device Sequence Number** | 1 |
| **Product Code** | FTL[24] |
| **Report Source** | Manufacturer |
| **Source Type** | Health Professional,User facility,Company Representative |
| **Reporter Occupation** | Physician |
| **Remedial Action** | Other |
| **Type of Report** | Initial |
| **Report Date** | 12/02/2011 |
| ***1* Device Was Involved in the Event** | |
| ***1* Patient Was Involved in the Event** | |
| **Date FDA Received** | 12/22/2011 |
| **Is This An Adverse Event Report?** | Yes |

**Is This A Product Problem Report?** No
**Device Operator** Health Professional
**Device Catalogue Number** PHY1015V
**Was Device Available For Evaluation?** No
**Is The Reporter A Health Professional?** Yes
**Event Location** Other
**Date Manufacturer Received** 12/02/2011
**Was Device Evaluated By Manufacturer?** Device Not Returned To Manufacturer
**Is The Device Single Use?** Yes
**Is this a Reprocessed and Reused Single-Use Device?** No
**Type of Device Usage** Initial

**Patient TREATMENT DATA**
**Date Received: 12/22/2011 Patient Sequence Number: 1**

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Page Last Updated: 04/30/2016

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